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| 09/541,462  | 03/31/2000  | Yue Xiong            | 5470-255            | 3846             |
| <div>20792      7590      10/17/2003</div> <div>MYERS BIGEL SIBLEY &amp; SAJOVEC</div> <div>PO BOX 37428</div> <div>RALEIGH, NC 27627</div> |             |                      |                     |                  |
| <div>EXAMINER</div> <div>RAMIREZ, DELIA M</div>   |             |                      |                     |                  |
| <div>ART UNIT      PAPER NUMBER</div> <div>1652      22</div>   |             |                      |                     |                  |

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/541,462

Applicant(s)

XIONG ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-48 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 and 17-48 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-6 and 14 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1,3,7 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

Claims 1, 3-48 are pending.

Applicant's amendment of claims 1, 3-4, 6-7, 13-16, in Paper No. 20, filed on 8/8/2003 is acknowledged.

As indicated in previous Office Action Paper No. 19, mailed on 5/6/2003, claims 8-12 and 17-48 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to an invention non-elected with traverse in Paper No. 17, filed 3/26/2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Oath/Declaration***

1. As indicated in previous Office Action Paper No. 19, the oath or declaration is defective. Applicants have indicated that a new oath or declaration will be submitted in a future communication. Therefore, the objection to the oath/declaration is maintained for the reasons of record.

### ***Priority***

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/166,927 is acknowledged. It is noted, however, that as indicated in previous Office

Action Paper No. 19, the oath/declaration refers to a different provisional application, i.e. 60/133,927.

***Drawings***

3. The formal drawings submitted on 8/8/2003 have been reviewed and are approved by a draftsman under 37 CFR 1.84 or 1.152.

***Claim Objections***

4. Claims 1, 3, 7, and 13 remain objected to because of the recitation of "ROC1". It is noted that claim 7 was inadvertently omitted from this objection in previous Office Action Paper No. 19. While Applicants argue that the term "ROC1" is not an abbreviation but rather the name of the protein, it is noted that the same protein, as evidenced by Kamura et al. (Science 284:657-661, April 1999; cited in previous Office Action Paper No. 19), has a different name, i.e. Rbx1 (ring box protein 1). As such, for clarity, it is suggested that the term "ROC1" be replaced with "Regulator of Cullins 1 (ROC1)" at least once to clearly indicate the correlation between ROC1 and its function. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, Second Paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection necessitated by amendment of claim 15.

7. Claim 15 is indefinite in the recitation of "expression vector encoding an antisense oligonucleotide" for the following reasons. As known in the art, nucleic acids encode polypeptides, therefore it is unclear as to how a vector can encode an oligonucleotide. For examination purposes, it will be assumed that the expression vector comprises any polynucleotide comprising the oligonucleotide. Correction is required.

***Claim Rejections - 35 USC § 112, First Paragraph***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 15 and 16 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. This rejection has been discussed at length in Paper No. 19 and is applied to amended claims 15 and 16 for the reasons of record and for the reasons set forth below.

11. Applicants argue that claims 13-16 have been amended such that the genus of nucleic acids claimed are adequately supported by the specification.

12. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection as it relates to claims 15 and 16. Claim 15 as indicated above (Claim rejections under 35 USC 112, second paragraph) is directed to any vector comprising a

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polynucleotide of any function comprising a 8-50 nucleotide fragment of the complete complement of the polynucleotide of SEQ ID NO: 1. Claim 16 is directed to a method of producing any protein of any function which comprises at least 20 amino acids of the polypeptide of SEQ ID NO: 2 (60 nucleotides of the polynucleotide of SEQ ID NO: 1). As such, while the specification discloses the structure and function of the polynucleotide of SEQ ID NO: 1/polypeptide of SEQ ID NO: 2, the functions of polynucleotides comprising fragments of the polynucleotide of SEQ ID NO: 1 or its complete complement, such as 60 nucleotides of the polynucleotide of SEQ ID NO: 1 or 8-50 nucleotides of the complete complement of the polynucleotide of SEQ ID NO: 1, have not been provided. As indicated in previous Office Action Paper No. 19, many functionally unrelated polynucleotides are encompassed by the claims, as evidenced by the teachings of Bork, Witkowski et al., Van de Loo et al., Seffernick et al. and Broun et al. discussed previously. In addition, many structurally unrelated polynucleotides are encompassed by the claims. The recited structural feature of the genera, i.e. at least 60 nucleotides of the polynucleotide of SEQ ID NO: 1 or 8-50 nucleotides of the complete complement of the polynucleotide of SEQ ID NO: 1, does not constitute a substantial portion of the genus as the remainder of the structure of the nucleic acids recited is completely undefined and the specification does not define the remaining structural features necessary for the members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

13. Claims 15 and 16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) an expression vector comprising the polynucleotide of SEQ ID NO: 1, and (2) a method for recombinantly producing the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for (1) an expression vector comprising any 8-50 nucleotides completely complementary to the nucleic acid of SEQ ID NO: 1 or homologs thereof as recited in claim 1, or (2) a method to produce any protein comprising any fragment of the polypeptide of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

14. This rejection has been discussed at length in Paper No. 19 and is applied to amended claims 15 and 16 for the reasons of record and for the reasons set forth below.

15. Applicants argue that the amendments made to claims 1, 13, and 16 render the previous scope of enablement rejection moot. According to Applicants, the claims now recite structurally and functionally related molecules and one of skill in the art can practice the claimed invention using no more than routine skill based on the specification and the knowledge in the art.

16. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 15 and 16. Claim 15 as indicated above (Claim rejections under 35 USC 112, second paragraph) is directed to any vector comprising a polynucleotide of any function comprising a 8-50 nucleotide fragment of the complete complement of the polynucleotide of SEQ ID NO: 1. Claim 16 is directed to a method of producing any protein of any function which comprises at least 20 amino acids of the polypeptide of SEQ ID NO: 2 (60 nucleotides of the polynucleotide of SEQ ID NO: 1). As indicated above, the specification

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while disclosing the structure and function of the polynucleotide of SEQ ID NO: 1/polypeptide of SEQ ID NO: 2, fails to disclose the functions of polypeptides encoded by polynucleotides comprising fragments of the polynucleotide of SEQ ID NO: 1 or its complete complement, such as 60 nucleotides of the polynucleotide of SEQ ID NO: 1 or 8-50 nucleotides of the complete complement of the polynucleotide of SEQ ID NO: 1. As indicated above, many functionally and structurally unrelated polynucleotides are encompassed by the claims. Furthermore, the teachings of Bork, Witkowski et al., Van de Loo et al., Seffernick et al. and Broun et al. discussed previously clearly indicate the unpredictability of assigning function based on structural homology. Therefore, one of skill in the art would have to go through the burden of undue experimentation to determine the function of the nucleic acids recited in the claims. As such, one cannot reasonably conclude that the specification is enabling for the full scope of the claims.

***Claim Rejections - 35 USC § 102***

17. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
18. Claim 1 was rejected under 35 U.S.C. 102(a) as being anticipated by Okresz (GenEMBL accession number AY052401) as disclosing the polynucleotide encoding the *A. thaliana* gene coding for the ROC1 protein disclosed by Applicants as prior art.
19. Claims 1, 13 and 14 were rejected under 35 U.S.C. 102(b) as being anticipated by Arino et al. (GenBank accession number CAA99155, August 1997).



20. In view of Applicant's amendment of claims 1, 13 and 14, and since neither Okrez nor Arino et al. teach (1) a polynucleotide which hybridizes under the stringent conditions recited in claim 1, (2) a polynucleotide which is 95% sequence identical to that of SEQ ID NO: 1, or (3) oligonucleotides consisting of 8-50 nucleotides of the complete complements of (1) or (2), these rejections are hereby withdrawn.

***Claim Rejections - 35 USC § 103***

21. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

22. Claims 5-7, and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Arino et al. (GenBank accession number CAA99155, August 1997).

23. In view of Applicant's amendment of claims 1 and 16, and since neither Okrez nor Arino et al., alone or in combination, teach an expression vector or a host cell comprising (1) a polynucleotide which hybridizes under the stringent conditions recited in claim 1, (2) a polynucleotide which is 95% sequence identical to that of SEQ ID NO: 1, or (3) 60 contiguous nucleotides of the polynucleotide of SEQ ID NO: 1, this rejection are hereby withdrawn.

24. Claim 15 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Arino et al. (GenBank accession number CAA99155, August 1997). Arino et al. teaches a polynucleotide which comprises several fragments of the polynucleotide of SEQ ID NO: 1 having at least 8 consecutive nucleotides. See alignment provided in previous Office Action Paper No. 19.

Claim 15 as interpreted above, is directed to an expression vector which comprises any polynucleotide comprising a fragment of 8-50 nucleotides of the complete complement of the

polynucleotide of SEQ ID NO: 1. As indicated in previous Office Action Paper No. 19, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a vector which comprises the complete complement of the yeast polynucleotide of Arino et al. A person of ordinary skill in the art is motivated to construct such a vector for further functional characterization of the yeast ROC protein since such a vector can produce a polynucleotide (mRNA) which can block expression of the yeast ROC gene. One of ordinary skill in the art has a reasonable expectation of success at making the vector since vector construction is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

#### *Allowable Subject Matter*

25. Claims 1, 3-7, 13-14 are allowable over the prior art.
26. Claims 1, 3, 7, and 13 would be allowable if at least claim 1 is rewritten as suggested above under "Claim Objections".

#### *Conclusion*

27. Applicant's amendment of claims 1, 3-4, 6-7, 13-16 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

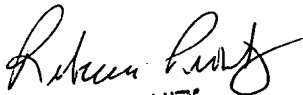
28. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
October 14, 2003

  
REBECCA E. PALUTY  
PRIMARY EXAMINER  
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1600